PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 5005	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/IT2004/000217	International filing date *(day/month/year)* 15.04.2004	Priority date *(day/month/year)* 22.04.2003
International Patent Classification (IPC) or national classification and IPC G06T5/00		
Applicant PROVINCIA ITALIANA DELLA CONGREGAZIONE DEI...		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 8 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
22.10.2004	02.08.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Martelli, L Telephone No. +49 89 2399-7416

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IT2004/000217

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-29 as originally filed

Claims, Numbers

1-18 filed with telefax on 22.11.2004

Drawings, Sheets

1/13-13/13 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	4,6-8,10,11,15-18
	No:	Claims	1-3,5,9,12-14
Inventive step (IS)	Yes:	Claims	7,8,15-18
	No:	Claims	1-6,9-14
Industrial applicability (IA)	Yes:	Claims	1-18
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

CITED DOCUMENTS

The following documents are referred to in this communication:

D1: WO 02/33649 A	(Souluer Farid)	25 April 2002	(2002-04-25)
D2 : US 5 836 872 A	(Tearney GJ et al)	17 November 1998	(1998-11-17)

Re Item V

V.1 Independent claim 1

D1 and D2 disclose a method of detecting and showing variations in the number and morphology of external skin lesions (see D1, page 1, lines 18-19 and page 25, line 30 to page 26, line 1; D2: column 2, lines 32-39), wherein, in order to automate the detection and the transmission of said variations (see D2, column 2, lines 2-3):
- digital images of the body surface of the tested subject are collected (see page 10, lines 6-7 and page 21, lines 15-16; according to page 22, lines 2-3 and 24-26, the characteristic of interest may be the tissue colour; see D2, column 5, lines 25 and 54; column 10, lines 16-19) after having divided the latter into one or more areas (see D1, page 9, line 1 and page 21, lines 16-17; see D2, column 5, lines 7-12; column 10, lines 34-35; column 11, lines 6-9) exactly located by means of spatial coordinates (see D2, column 11, line 60; column 12, lines 1-3; column 14, line 10) in a system of coordinated axes fixed with respect to predetermined unchanged reference point of the subject (i.e. body parts such as shoulders, arms and neck: see D1, page 9, lines 11-22, as well as page 10, lines 1-8; page 21, lines 17-18; page 24, lines 15-16),
- the images being stored in a suitable data base (see D1, page 24, lines 16-19; see D2, column 14, lines 2-3; column 25, lines 53-55)
- to be then compared with corresponding images collected at distance of time (see D1, page 10, lines 7-8 and page 24, line 19; see D2, column 14, lines 9-11),
- thus producing a signal of any variation in the number, morphology and colour of the lesions (see D1, page 24, line 28 to page 25, line 3; see D2, column 14, lines 11-12) and wherein
- the relative spatial position between the subject body surface and the point of view from which said images are collected being the same for each subsequent

corresponding image (see D1, page 9, line 20; see D2, column 5, lines 63-65).

So D1 discloses all the features of claim 1; this claim is therefore not new (Article 33(2) PCT). On the other hand, D2 does not disclose that the coordinate axes are fixed on the examined subject.

V.2 Dependent claims 2-6, 9-11

The documents D1-D2 disclose the following features of these dependent claims:

Claim 2: quadrants (see D1, page 9, line 1; page 21, lines 15-17; page 23, lines 2-4; see D2, column 7, lines 6-7); reference anatomical points (see D1, page 9, line 13); collect and store images (see page 10, lines 6-8); numbering skin lesions (see D1, page 23, lines 2-4; page 25, line 30 to page 26, line 1; see D2, column 7, lines 25-29 and 33-36); storing images and data of skin lesions (see D1, page 23, line 4; see D2, column 10, lines 25-28); compare with previous data (see D1, page 24, lines 16-17); highlight new skin lesions (see page 23, lines 18-20); storing data on detected differences (see D1, page 25, line 6).
Claim 3: anthropometric data input (see D1, page 9, lines 11-14); select parts of body surface (see D1, page 9, line 1); positioning the patient on the basis of the anatomical landmarks (see D1, page 9, line 20 and page 10, lines 1-5); calculate coordinates of image centre (see D1, page 9, lines 16-17; page 10, lines 6-8 and 24-27); collect and store images (see D1, page 10, lines 7-8); analyse stored images (see D1, page 10, lines 21-23); compare analysed images (see D1, page 22, lines 24-26; page 23, lines 2-4).
Claim 4: locate objects not related to the skin (see D2, column 16, lines 12-15); locate hairs (see column 16, lines 23-25); locate lesions of interest (see D2, column 16, lines 15-17 and 23-25).
Claim 5: constant spatial position of detecting apparatus and detected subject (see D1, page 5, lines 63-65; see D2, column 9, line 20).
Claim 6: sit down (see D2, column 5, lines 36-37).
Claim 9: uniform illumination and from different angles (see D1, page 10, line 14).
Claim 10: non-human pixels (see D2, column 16, line 12), ablate hair images (see D2, column 16, lines 24-25), grey levels (see D2 column 18, lines 56-57; column 23,

lines 21-14), background construction (see D2, column 16, lines 37 and 53), levels of identification (see D2, column 17, lines 64-65; column 18, lines 5 and 8), evidence threshold (see D2, column 18, lines 34-37); recognise pigmented areas (see D2, column 18, lines 5-9); characterise pigmented areas (see D2, column 18, lines 10-17); differentiate pigmented areas (see D2, column 19, lines 28-45).
Claim 11: see D2, column 26, lines 12-16.

So the claims 2, 3, 5 and 9 are not new (Article 33(2) PCT) with reference to D1; the claims 4, 6, 10 and 11 are not inventive (Article 33(3) PCT) because the differences between these claims and the subject-matter of D1 and D2 relate to features which the skilled person would use in any way to provide a method for detecting skin lesions starting from D1 or D2.

The first alternative of claim 5, concerning the fixed point of view for each skin portion, is not disclosed in the cited documents

V.3 Dependent claims 7 and 8

The subject-matter of claim 7 is characterised over D1 in that the body surface is subdivided into images so that the edges of the images are partially overlapped so as to allow a comparison even when modifications of the body of the tested subject take place between subsequent tests.

The problem to be solved may be considered as to ensure that images are taken of the selected body parts even if the dimensions of the patient vary during different tests (see the description, page 13, lines 21-25).
This problem and the corresponding solution are not addressed in the available prior art documents. Hence claim 7 fulfils the requirements of Article 33(2) and (3) PCT.

Claim 8 depends on claim 7 and as such also meets the requirements of PCT with respect to novelty and inventive step.

V.4 Independent claim 12

D1 and D2 describe an apparatus for detecting images of skin lesions (10, see D1, page 1, lines 23-24), the apparatus comprising:

- an application software for processing fine graphic data provided with algorithms able to provide a discrete set of the detected images (see D1, page 20, lines 27-29);

- a data base for the statistic analysis of data of interest (see D1, page 24, lines 16-17);
- a data processing portion for clinic, personal data of the subjects for storing and listing images of each patient upon his/her visiting (see D1, page 24, lines 16-17);
- a reference surface (66, 71) provided with anthropometrical references with respect to which the tested subject is positioned (see D1, page 9, lines 4-6);
- means for lighting uniformly (136) without shadows the zones of the subject body surface to be detected (see D1, page 10, lines 9-14);
- image collection means (134, see D1, page 10, line 6);
- means for supporting the image collection means with respect to the patient (D1: see figure 5; means for driving under control: see D2, column 11, lines 36-46);
- interface means for controlling the data collection and transmission to suitable storing and processing means (see D1, page 7, lines 6-7);
- a computer connected to such interface means (see D1, page 10, line 7);
- a high definition monitor (see D1, page 7, lines 7-9);
- means for controlling the correct repositioning of the subject (see D1, page 9, line 29 to page 10, line 5).

Hence D1 describes all the features of claim 12. This claim is not new (Article 33(2) PCT).

V.5 Dependent claims 13 and 14

D1 contains the following features of these claims:

Claim 13: anthropometric references (see D1, page 9, lines 11-17).
Claim 14: automatic control (see D1, page 9, lines 17-22).

So these claims are not new (Article 33(2) PCT).

Claims

1. A method of detecting and showing variations in the number and/or the morphology of the external skin lesions of dermatological interest, characterized in that in order to automate the detection and the transmission of said variations digital images of the body surface of the tested subject are collected after having divided the latter into one or more areas exactly located by means of spatial coordinates in a system of coordinated axes fixed with respect to predetermined unchanged reference points of the subject, the images being stored in a suitable data base to be then compared automatically with corresponding images collected at distance of time, thus producing a signal of any variation in the number and/or the morphology/colour of the lesions; the relative spatial position between the subject body surface and the point of view from which said images are collected being the same for each subsequent corresponding image.

2. The method according to the preceding claim, characterized in that there are provided the following operating steps:

A. subdividing the body surface into quadrants with suitable size;

B. selecting predetermined reference or "repere" anatomic points so that the following detection may have repere points able to collimate the body quadrants of the same subject;

C. collecting and storing images with high definition relative to the above-mentioned quadrants;

D. processing the stored images to perform the following operations:

- locating, numbering and measuring all of the skin lesions present in each quadrant;
- storing images and data relative to said skin lesions;
- if the subject is not a new subject, comparing collected images and corresponding data with previously stored images and data of the same subject;
- highlighting and/or transmitting the new skin lesions in each quadrant and/or highlighting the morphological/colorimetric variations in one or more previously located skin lesions;
- storing data relative to the detected differences.

3. The method according to claim 1, characterized in that there are provided the following steps:

a) inputting anthropometrical data of the subject to be tested;

b) selecting the portion(s) of the body surface to be detected;

c) positioning the subject on the basis of the predetermined reference and/ore repere points

d) calculating the coordinates of the centre of each image and the direction of collection of each of

them;

e) collecting and storing said images automatically and repeatedly;

f) analysing the stored images to locate the existing skin lesions of interest;

g) comparing the analysed images with the images stored and analysed previously, if any, to highlight the presence of any numeric and/or colorimetric difference.

4. The method according to claim 2 or 3, characterized in that said processing or analysis of the stored images provides essentially:

- locating objects contained in the image other than skin (underwear, background, etc.);
- locating structures that can produce false positives (hairs, spots produced by natural orifices or shadows, tattoos, etc.); and
- locating lesions of interest to be compared and ignoring objects and/or structures of the two preceding items.

5. The method according to any preceding claim, characterized in that in order for any variation of the collected images not relating the state of the skin lesions to be suppressed or minimized, it is provided that each skin portion of the same subject is detected in subsequent times from a predetermined and fixed point of view, or that the spatial positions of the detection apparatus and the tested subject (or

his/her skin portion) are constant.

6. The method according to the preceding claim, characterized in that the tested subject is allowed to sit down to essentially the same position in any test following the first.

7. The method according to claim 5, characterized in that the body surface of tested subject is segmented or sub-divided into images is performed so that the edges of the images are partially overlapped so as to allow a comparison even when modifications of the body of the tested subject take place between subsequent tests.

8. The method according to the preceding claim, characterized in that the number of collected images for a determined patient is always the same, even if the patient increases in weight and/or height in time.

9. The method according to any preceding claim, characterized in that the patient is illuminated uniformly and from different angles so as to avoid portions in the shade at the areas to be detected.

10. The method according to claim 3, characterized in that step f) of image analysis includes the following steps:

- recognizing not human pixels;
- ablating piliferous appendages by parametrization

software;

- constructing grey levels referred to the weight of blue;
- constructing the background (smoothing);
- constructing levels of identification of the pigmented areas (spot objects);
- calculating mathematically the evidence threshold;
- recognizing the pigmented areas (spot objects);
- characterizing the pigmented areas in terms of their specific qualities (spot objects);
- differentiating the pigmented areas (spot objects) of the background noise (hair, underwear, tattoos, orifices, etc. objects).

11. The method according to claim 3, characterized in that step g) of image comparison includes the following steps:

- collimating frames (algorithm 1);
- rotating/translating in scale;
- calculating the known connections;
- translating the pigmented areas (spot objects) to an assigned range to minimize the discards;
- calculating the differences (minus and/or plus dimensional - variation of the inner colour);
- optimising: if the number of erroneous connections is greater than three or if the secondary translation of the pigmented areas (spot objects) is greater than an assigned level (for example 100 pixels), a second collimation method (algorithm 2) is performed.

12. An apparatus for detecting images by the method according to the preceding claims, characterized in that there is provided in combination:

a) an application software for processing fine graphic data (skin lesions) provided with algorithms able to provide a discrete set of the detected images (matrices of calculation);

b) a data base for the statistic analysis of data of interest;

c) a data processing portion for clinic, personal data of the subjects for storing and listing the images of each patient upon his/her visiting (mode of the case history);

d) a reference surface provided with anthropometrical references with respect to which the tested subject is positioned;

e) means for lighting uniformly without shadows the zones of the subject body surface to be detected;

f) image collection means;

g) means for supporting and/or driving under control such image collection means with respect to the patient;

h) interface means for controlling the data collection and transmission to suitable storing and/or processing means;

i) at least a computer connected to such interface means;

j) at least a high definition monitor or video or other display means of the known type;

k) means for controlling the correct repositioning of the subject.

said means for supporting and/or driving said image collection means being controlled so as the relative spatial position of the subject body surface and the point of view from which the images are collected are the same for each subsequent corresponding image.

13. The apparatus according to the preceding claim, characterized in that said anthropometrical references located in the reference surface for positioning the subject are able to locate the repere points which are significant for different somatic types as well as for the same patient subjected to several next detections so that defined, significant body areas that can be overlapped are obtained to guarantee a correct collimation of the collected images.

14. The apparatus according to the preceding claim, characterized in that it is provided with a computer, controlled by an assistant, which controls and manages the apparatus in a completely automatic way.

15. The apparatus according to claim 12, characterized in that said support and drive means of the image collection means is able to position the

latter perpendicular to the area of the body surface to be detected and at a constant distance therefrom.

16. The apparatus according to claim 12, characterized in that it is provided with storing means which store the position and the orientation taken by said image collection means for each collected image, during the first session so that corresponding images are collected in the following sessions exactly with the same position and orientation, thus providing following images perfectly corresponding and comparable with those of the preceding session.

17. The apparatus according to claim 12, characterized in that it is provided with calculating means which calculate the positions of the images to be collected, so that the edges of images adjacent to one another are partially surmounted, thus forming an overlap.

18. The apparatus according to the preceding claim, characterized in that the overlap of the image edges adjacent to one another varies preferably from a maximum equal to half the height and half the width of the image to a minimum that can be zero (images with coincident edges).